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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,236	11/19/2003	John D. Nguyen	CSI-2013C1	9909

7590 12/02/2008
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EXAMINER	
WOO, JULLAN W	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/718,236

Applicant(s)

NGUYEN ET AL.

Examiner

Julian W. Woo

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18, 21, 24 and 25 is/are allowed.
- 6) ☒ Claim(s) 17, 19, 20, 22 and 26-29 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 2, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 17, 19, 20, 22, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup (5,972,024) in view of Pyka et al. (5,002,563), and further in

view of Krajicek (5,413,597). Northrup discloses the invention substantially as claimed. Northrup discloses, at least in figures 4-9 and col. 4, lines 5-54; a clip assembly and a method of holding two tissue parts together, where the assembly and method include two clips (60) each having two end points, a proximal end point and a distal end point, the proximal end point and the distal end point being separated from each other when the clip is held in an open configuration; two tissue penetrating needles (40) each releasably connected to one of the two end points (see also col. 4, lines 61-65, where the needles (and sutures) may be cut from, i.e., released from the clips), and a flexible connector (e.g., 310 in fig. 9) connecting the other end points of the two clips together; where the method includes penetrating and completely pulling one of the needles through a tissue part (e.g., 320 in fig. 9) and penetrating and completely pulling the other of the needles through an adjacent tissue part (e.g., also at 320) while the clips are each in an open configuration; pulling the needles until each of the clips is hooked to a corresponding one of the tissue parts, and where the two tissue parts are held together by the flexible connector stretched between the clips. However, Northrup does not disclose that the clip has a tendency to return to a naturally closed configuration and is formed of a wire made of shape memory material. Northrup also does not specifically disclose that the clips each include a stopper connected to one of the two end points of the clip. Northrup does not disclose that the flexible connector is an apparatus or an artificial element, and that the flexible connector forms a loop when stretched between the clips.

Pyka et al. teach, at least in figures 5A-6B2 and col. 4, lines 26-58; a clip having a tendency to return to a naturally closed configuration from an open configuration, where the clip is formed of a wire made of shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply a clip as taught by Pyka et al. in the device and method of Northrup. Such a clip would help draw tissue parts together and join them without requiring the extra time for crimping of the clip.

Northrup further discloses in figures 10-12 and col. 5, lines 39-51, a clip (460) applicable to the abovementioned clip assembly, where the clip includes a stopper (490) connected to one of the two end points of the clip. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply clip 460 in the clip assembly. Such a clip with a stopper, such as element 490, would serve to anchor the clip more securely against a tissue structure.

Additionally, Krajicek teaches, at least in figure 1 and in col. 1, line 62 to col. 2, line 14; an artificial flexible connector usable for the anastomosis as disclosed by Northrup or Northrup in view of Pyka et al. The flexible connector of Krajicek forms a loop, i.e., elements 1, 2, and/or 3 form a circumferential structure at the end of the connector. It would have been obvious to one having ordinary skill in the art to apply an artificial flexible connector, in view of Krajicek, in the apparatus and method of Northrup or Northrup in view of Pyka et al. Such a connector would be useful for replacing or repairing a defective vascular structure, and it would effectively prevent

leakage around the clips when the connector and clips are joined to another vascular structure.

Allowable Subject Matter

4. Claims 18, 21, 24, and 25 are allowed.
5. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a clip assembly and a method with the clip assembly for holding two tissue parts together, where the assembly and method include, inter alia, two clips, each clip having an open configuration and tending to return to a naturally closed configuration; two tissue penetrating needles connected to the clips via flexible members, and a flexible connector connecting the clips, where the clip assembly has a releasing means for normally keeping the two clips in the open configuration and releasing the clips to become separated from the flexible members and allowing the clips to return to the closed configuration.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a clip

assembly including, inter alia, two clips, each clip having an open configuration and tending to return to a naturally closed configuration; two tissue penetrating needles connected to the clips via flexible members, and a flexible connector connecting the clips, where the clip assembly has a releasing means for normally keeping the two clips in the open configuration and releasing the clips to become separated from the flexible members and allowing the clips to return to the closed configuration.

.As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

8. Applicant's arguments filed on September 2, 2008 have been fully considered but they are not persuasive. That is, with respect to arguments regarding the rejection of claim 17 based on Northrup: Northrup indeed discloses flexible connector 310 (as modified by Krajcek to be an apparatus) connecting end points of two clips together. In other words, when the clips are directly attached to element 310, a circumferential portion of element 310 connects the two clips. The ends of the clips are connected by virtue of the attachment of both clips to element 310.

With respect to arguments regarding the rejection of claim 20, Northrup indeed discloses two tissue "parts" in structure 320, where "part" has been given its broadest reasonable interpretation. That is, "part" can mean a "portion of" or a "side of" a singular object. Element 320 has diametrically opposed parts or portions through which two needle respectively pass. Also, the two parts are spanned by, i.e., connected by

Art Unit: 3773

element 310--the flexible connector--when element 310 is joined to the parts of element 320.

Moreover, the needles are indeed releasably connected to the clip through a flexible member. That is, the needles are connected to clips *via* flexible members or sutures, and the needles may be released from the clips by cutting of the sutures, as disclosed by Northrup.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

December 3, 2008